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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

SWITZER, JULIET CAROLINE

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
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1634

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/813,693

Applicant(s)

TABOR ET AL.

Examiner

Juliet C. Switzer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 11 and 24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 11 and 24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) *9/6*
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/9-6/7/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____

DETAILED ACTION

1. Applicant's preliminary amendment canceling claims 2-10, 12-23 and 25-123 have been entered. Claims 1, 11, and 24 are pending and are examined herein.
2. Applicant is requested to update the first line of the specification to indicate that the parent application is now abandoned.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Scherzinger *et al.* (Eur. J. Biochem 72, 543-558 (1977)).

Scherzinger *et al.* teach a method of amplifying a template DNA molecule comprising incubating said template DNA molecule with a reaction mixture comprising bacteriophage T7 DNA polymerase, the T7 gene-4 protein (designated the T7 DNA-priming protein), the T7 DNA-binding protein, at a constant temperature of 30° C to produce amplified product, (p. 546, Standard Assay and Isotope Transfer Experiments). In the assay taught by Scherzinger *et al.* the production of amplified product does not require exogenously-added oligonucleotide primers and said template DNA molecule does not have a terminal protein covalently bound to either 5' end.

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Scherzinger *et al.* also teach this method with the use of E. coli DNA-binding protein (p. 549, Col. 2). It is noted that the T7 gene-4 protein has provides both helicase and primase activities, as noted in the specification page 5 lines 18-20.

5. Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Engler *et al.* (The Journal of Biological Chemistry (1993), Vol. 258, No. 18, pp.11197-11203).

Engler *et al.* teach a method of amplifying a template DNA molecule comprising incubating said template DNA molecule with a reaction mixture comprising bacteriophage T7 DNA polymerase, the T7 gene 4 protein, the T7 gene 6 protein and T7 DNA ligase, at a constant temperature of 30° C to produce amplified product, (p. 11199, Assay for Conversion of Single-stranded Circular DNA to Covalently Closed Duplex Circular DNA). In the assay taught by Engler *et al.* the production of amplified product does not require exogenously-added oligonucleotide primers and said template DNA molecule does not have a terminal protein covalently bound to either 5' end. The method also includes ATP and CTP. It is noted that the T7 gene-4 protein has provides both helicase and primase activities, as noted in the specification page 5 lines 18-20.

6. Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Applegren *et al.* (Journal of Cellular Biochemistry 59:91-107 (1995)).

Applegren *et al.* teach a method of amplifying a template DNA molecule comprising incubating said template DNA molecule with a reaction mixture comprising a DNA polymerase,

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a helicase, a primase, a ligase, phosphocreatine and creatine kinase at a constant temperature of 35° C to produce amplified product, (p. 94, In Vitro SV40 DNA Replication Assay). In the reaction mixture of Applegren *et al.* the polymerase, helicase, primase, and ligase are contained in the protein fraction (see Fig. 8). In the assay taught by Applegren *et al.* the production of amplified product does not require exogenously-added oligonucleotide primers and said template DNA molecule does not have a terminal protein covalently bound to either 5' end.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scherzinger *et al.* in view of Sorge *et al.* (US 5556772).

Scherzinger *et al.* teach a method of amplifying a template DNA molecule comprising incubating said template DNA molecule with a reaction mixture comprising bacteriophage T7 DNA polymerase, the T7 gene-4 protein (designated the T7 DNA-priming protein), the T7 DNA-binding protein, at a constant temperature of 30° C to produce amplified product, (p. 546, Standard Assay and Isotope Transfer Experiments). In the assay taught by Scherzinger *et al.* the production of amplified product does not require exogenously-added oligonucleotide primers and said template DNA molecule does not have a terminal protein covalently bound to either 5' end. Scherzinger *et al.* also teach this method with the use of E. coli DNA-binding protein (p. 549, Col. 2).

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Scherzinger *et al.* do not teach methods in which the reaction mixture comprises a T7 DNA polymerase modified to have reduced 3' to 5' exonuclease activity.

Sorge *et al.* teach a composition which comprise a DNA polymerase with substantial 3'-5' exonuclease activity and DNA polymerase modified to have reduced 3' to 5' exonuclease activity (Col. 2, lines 63-66). They further teach that T7 polymerase is a polymerase that possesses substantial 3' to 5' exonuclease activity (Col. 3, lines 44-47) and that modified bacteriophage T7 DNA polymerase is polymerase that has reduced 3' to 5' exonuclease activity (Col. 4, lines 5-10).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used a composition as taught by Sorge *et al.* in the reaction mixture taught by Scherzinger *et al.* The ordinary practitioner would have been motivated to include such a composition in the method taught by Scherzinger *et al.* in order to provide an improved system for in vitro DNA synthesis since Sorge *et al.* teach that their compositions provide "increases synthesis product yield, increased transcription product length, and the synthesis of polynucleotides that can not be synthesized by a given polymerase alone (Col. 3, lines 22-27)."

Conclusion

9. This is a continuation of applicant's earlier Application No. 09/480878. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday, Tuesday, or Thursday, from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached by calling (571) 272-0735.

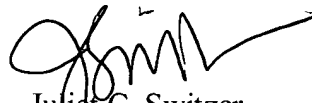
The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is

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(866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Juliet C. Switzer
Primary Examiner
Art Unit 1634

June 22, 2006